IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

UNITED STATES OF AMERICA, Plaintiff, v. DEVIN MICHAEL TEW, Defendant.	**MEMORANDUM DECISION AND ORDER DENYING MOTION TO DISMISS** Case No. 2:24-cr-00075-JNP District Judge Jill N. Parrish

People may excel in multiple distinct pursuits. William Moulton Marston, a psychologist and comic-book writer, invented the systolic blood-pressure test and created the character Wonder Woman. The same Yamaha company for years dealt in pianos and motorbikes.

Devin Michael Tew, Defendant in this case, generated hundreds of thousands of dollars from operating two different websites over at least four years: poppyseedwash.com and utahspermdonor.org. On the first website, he sold poppyseed kits his customers could use to brew their own opioid-rich poppyseed tea for personal consumption. On the second, he sold and shipped his semen to women hoping to conceive a baby through a low-cost at-home insemination process.

The government caught wind of Mr. Tew's activities and indicted him for possession of drug-manufacturing paraphernalia in violation of 21 U.S.C. § 843(a)(6) (Count 1) and failure to follow regulations governing the manufacture and distribution of human tissue in violation of 42 U.S.C. §§ 264 and 271(a) (Count 3), among other things. Mr. Tew moves to dismiss Counts 1 and 3 of his indictment under Rule 12(b)(3)(B)(v) of the Federal Rules of Criminal Procedure for failure to state an offense.

The court concludes that the facts as alleged by the government, if proven, would support a conviction on both counts and accordingly DENIES Mr. Tew's motion to dismiss.

BACKGROUND

In resolving Mr. Tew's motion to dismiss, one preliminary issue is whether the court may consider factual allegations contained in the parties' briefing and attached exhibits. Typically, "[a]n indictment should be tested solely on the basis of the allegations made on its face." *United States v. Hall*, 20 F.3d 1084, 1087 (10th Cir. 1994). That said, the Tenth Circuit has held that a district court may test an indictment at the pretrial stage "where the operative facts are undisputed and the government fails to object to the district court's consideration of those undisputed facts." *Id.* at 1088. That decision, *United States v. Hall*, surveyed several prior decisions from the Tenth Circuit upholding district courts' decisions "to go beyond the allegations of the indictment and make predicate findings of fact" based on, for example, an evidentiary hearing or grand-jury subpoena duces tecum. *Id.* at 1087–88.

In this case, the court has before it a bare-bones indictment that simply parrots the statutory language (as is typical of indictments) plus the allegations contained in the briefing and attached exhibits. The indictment alone is inadequate for resolving Mr. Tew's motion because it does not allege any facts to substantiate the charges it contains. For example, Count 1 accuses Mr. Tew of "knowingly and intentionally possess[ing] materials which may be used to manufacture a controlled substance, knowing, intending, or having reasonable cause to believe that the said materials would be used to manufacture a controlled substance [in an unauthorized manner]." ECF No. 1, at 2. It does not suggest what the "materials" were and which "controlled substance" could be manufactured using them. Count 3 similarly accuses Mr. Tew of "violat[ing] regulations promulgated under Section 264 of the Public Health Act (42 U.S.C. § 264), to wit: regulations

found in 21 C.F.R. §§ 1271.145 and 1271.10(b) governing the prevention of the transmission and spread of communicable diseases related to the manufacture and distribution of human cells, tissues and cellular and tissue-based products . . . .” *Id.* at 3. It nowhere refers to semen.

The court concludes that it is appropriate here to go beyond the face of the indictment and consider the allegations in the parties’ briefing because those allegations are necessary for resolving Mr. Tew’s motion to dismiss and the material facts are undisputed. What follows is a simplified recitation of the material facts viewed in the light most favorable to the government. *United States v. Sharpe*, 438 F.3d 1257, 1258–59 (11th Cir. 2006).

As noted above, one of Mr. Tew’s businesses involved selling poppyseed kits for customers to brew their own poppyseed tea. Some background on poppy seeds and the regulation of poppy seeds is helpful for understanding Mr. Tew’s activities in this area. Poppy seeds, which as their name suggests are the seeds of the poppy plant, have a variety of uses in the pharmaceutical and food industries. Under the federal Controlled Substances Act, 21 U.S.C. §§ 801 et seq., opium poppy plants—except the seeds—are a Schedule II controlled substance. 21 U.S.C. § 802(19)–(20); *id.* § 812(Schedule II)(a)(3). That’s because poppy plants produce in addition to seeds a milky substance known as opium latex from which opiate alkaloids like morphine, codeine, and thebaine—all of which are themselves controlled substances—can be extracted. When the seeds are first harvested, they are coated in opium latex; the opium latex is later removed to prepare the seeds for sale in the retail food market (a process called washing). Poppy seeds that have not had their opium latex removed are called unwashed, unprocessed, or organic. As one would expect, these seeds have a higher opiate alkaloid content than their washed or processed counterparts. Consumers wishing to achieve a high similar to that created by pharmaceutical opioids may ingest the opiate alkaloids found in opium latex by brewing and drinking a tea made by steeping large

quantities of unwashed or unprocessed poppy seeds in water. If ingested in sufficient quantities, poppyseed tea can cause loss of consciousness or even death. (Although unwashed poppyseeds are coated in opium latex, they are still exempted from regulation under the Controlled Substances Act. *United States v. McCarthy*, No. 23-cr-00359, 2025 WL 360952, at *6–7 (N.D. Okla. Jan. 31, 2025).)

Sometime before 2018 and continuing through at least 2022, Mr. Tew sold poppyseed kits on the poppyseedwash.com website. The website specifically marketed unwashed poppy seeds for use in making poppyseed tea and touted its medicinal benefits. Each poppyseed kit contained a package of unwashed poppy seeds along with a water bottle and instructions for brewing the tea in the bottle. The water bottles were specially designed to strain out the seeds after the tea was brewed and ready for consumption.

Mr. Tew was notified several times that third-party observers—the government as well as private online marketplaces—understood him to be marketing his poppyseed kits with the intention and expectation that his customers would manufacture and consume drugs unlawfully. For example, the U.S. Food and Drug Administration ("FDA") sent him a letter in July 2018 warning him that "[t]he claims on [his] product label and websites establish[ed that] the product [wa]s a drug under [the Food, Drug, and Cosmetic Act]" and that "introducing or delivering th[at] product . . . into interstate commerce . . . violate[d] the Act." ECF No. 30-1, at 1. The warning letter cited several statements from Mr. Tew's website and his business's social-media accounts for support, such as the following:

- "Poppy seeds fall in the opioid drug class, which is any chemical that resembles morphine or other opiates in its pharmacological effects." *Id.*

- "Q: What kinds of chemically similar drugs can Poppyseed Wash rotate with or replace? A: Opiates: morphine, diacetylmorphine (heroin), codeine.[]Opioids: (opiates above), hydrocodone (lortab,[]norco, vicodin), oxycodone (percocet,[]oxycontin), demerol, fentanyl, buprenorphine (suboxone subutex), methadone." *Id.* at 2.
- "Q: What side effects are possible? A: Poppy seed tea has many of the same possible side effects that other opioids have including: drowsiness, dehydration respiratory depression, constipation and nausea." *Id.*

The letter directed him to "take prompt action to correct all violations associated with the products [he] market[ed]" because "[f]ailure to promptly correct th[o]se violations [could] result in enforcement action." *Id.* at 4. The letter also instructed him to "notify [the FDA office] in writing within fifteen (15) working days from [the date of] receipt of th[e] letter as to the specific steps [he] ha[d] taken to correct the violations" and offered him a chance, if he believed his products did not violate the Act, to "include [his] reasoning and any supporting information for [the office's] consideration." *Id.* eBay, for its part, sent Mr. Tew an email notification indicating that his listing for poppyseedwash.com was removed "because it didn't follow [the site's] illegal drugs and drug paraphernalia policy." ECF No. 30, at 5.

Alongside his web-based poppyseed business, Mr. Tew made his own semen available for purchase online at utahspermdonor.org. The website made a variety of false claims, presenting his company as a nonprofit and leading consumers to believe that they could choose sperm from one of several pre-screened donors all over the state when in reality Mr. Tew was the only donor (and, he does not dispute, he did not comply with FDA regulations for human reproductive tissue). Customers could purchase an at-home insemination kit (what the website called a "Home Donor Kit") containing "(1) Vial of fresh sperm from donor Mich Tew," "(1) Soft cup for insemination

(suggested method)," (1) Syringe for insemination (alternative method)," (7) Ovulation tests (in case you need to test next month)," "(2) Pregnancy Tests (to confirm pregnancy)," and instructions for use. *Id.* at 6.

In due course, the government charged him with violations of various laws arising from his poppyseed and semen businesses—namely, unlawful possession of drug-manufacturing paraphernalia (Count 1), introduction into interstate commerce of any drug that is misbranded (Count 2), and failure to follow regulations governing manufacture and distribution of human tissue (Count 3), plus three counts of structuring a transaction to evade reporting requirements (Counts 4, 5, and 6). Mr. Tew now moves to dismiss Counts 1 and 3 on the grounds that the government's allegations fail to state an offense.

ANALYSIS

Under Rule 12(b)(3)(B)(v), the court may dismiss an indictment (or part of an indictment) if the government's well-pleaded allegations on their face fail to establish the elements of the offense charged. *United States v. Debora Marquez*, No. 2:22-cr-00104, 2023 WL 2346318, at *1 (D. Utah Mar. 3, 2023). That is, "a pretrial dismissal is essentially a determination that, as a matter of law, the government is incapable of proving its case beyond a reasonable doubt." *Hall*, 20 F.3d at 1088 (emphasis removed).

I. Sale of Poppyseed Kits

Once again, Count 1 of the indictment charges Mr. Tew with unlawful possession of drug-manufacturing paraphernalia in violation of 21 U.S.C. § 843(a)(6). That section makes it unlawful to knowingly or intentionally "possess any three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material which

may be used to manufacture a controlled substance or listed chemical, knowing, intending, or having reasonable cause to believe, that it will be used to manufacture a controlled substance." *Id.*

As the government sees it, Mr. Tew knowingly "possess[ed] . . . equipment . . . [or] product"—specifically, seed-straining water bottles—"knowing[and] intending . . . that [they] w[ould] be used to manufacture a controlled substance"—in particular, morphine, codeine, and thebaine. *Id.* According to Mr. Tew, the government's theory fails for two reasons: first, water bottles fall outside the scope of § 843(a)(6), and second, poppy seeds are specifically excluded from the statute's list of controlled substances, *see id.* § 802(19)–(20). The court is not persuaded.

Begin with the issue of whether the water bottles fall outside the scope of the statute. When interpreting a statute, the court must "examin[e] the statute's plain language, and if the statutory language is clear, [the] analysis ordinarily ends." *Rocky Mountain Wild v. Dallas*, 98 F.4th 1263, 1291 (10th Cir. 2024) (internal quotation marks omitted). The plain meaning of a statute can often be discerned from "the statute's text, structure, purpose, history, . . . [and the] ordinary meaning [of statutory terms]." *Id.* (internal quotation marks omitted).

With these basic principles in mind, the court turns to consider whether water bottles are captured in the first portion of § 843(a)(6): "any three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule, or any equipment, chemical, product, or material." 21 U.S.C. § 843(a)(6). On its face, the statute uses the phrase "any equipment . . . [or] product." *Id.* "The adjective 'any' is . . . a broad term" indicating that anything that is "equipment" or a "product" can come within the statute's scope. *See City of San Francisco v. EPA*, 145 S. Ct. 704, 716 (2025). *Merriam-Webster*'s dictionary defines "equipment" as "the set of articles or physical resources serving to equip a person or thing" and provides the example of "implements used in an operation or activity." *Equipment*, MERRIAM-WEBSTER, https://www.merriam-webster.com/

dictionary/equipment. The *American Heritage Dictionary* lists "paraphernalia" as a synonym of "equipment." *Equipment*, AM. HERITAGE DICTIONARY, https://ahdictionary.com/word/search.html?q=equipment. Water bottles, particularly specialized ones like those Mr. Tew sold in his poppyseed kits, fit neatly into these definitions of "equipment." Those water bottles were implements or paraphernalia used for the activity of brewing poppyseed tea. And it is beyond reasonable dispute that the water bottles were "products." *See, e.g.*, *Product*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/product (defining "product" as "something produced").

Mr. Tew resists this straightforward analysis, observing that the very broad words "any equipment . . . [or] product" in the statute are preceded by the far narrower words "three-neck round-bottom flask, tableting machine, encapsulating machine, or gelatin capsule." 21 U.S.C. § 843(a)(6). Here, Mr. Tew essentially invokes two well-established canons of statutory interpretation: *noscitur a sociis* and *ejusdem generis*. *Noscitur a sociis* literally means "a word is known by the company it keeps." *Yates v. United States*, 574 U.S. 528, 543 (2015) (plurality op.). It "counsels that a word is given more precise content by the neighboring words with which it is associated," *United States v. Williams*, 553 U.S. 285, 294 (2008). Relatedly, under the canon of *ejusdem generis*, "a general or collective term at the end of a list of specific items is typically controlled and defined by reference to the specific classes that precede it." *Fischer v. United States*, 603 U.S. 480 (2024) (cleaned up).

In fairness to Mr. Tew, the narrowing effect of these canons and the four specifically named items is somewhat in tension with the broad function of § 843(a)(6) in the context of the whole Controlled Substances Act. To understand how § 843(a)(6) fits into the overall scheme of regulating controlled substances, consider the structure of the Act. Parts A and B of the Act, among

other things, define controlled substances and set out the schedule of those controlled substances. *See* 21 U.S.C. §§ 802, 812. Part C then sets out how someone who wishes to manufacture or distribute a controlled substance may obtain approval for doing so legally. *See id.* §§ 821–832. Part D follows with offenses and penalties, laying out prohibited acts in §§ 841, 842, and 843. Section 841 broadly criminalizes the direct manufacture, distribution, or possession of controlled substances, and § 842 criminalizes activities that undermine the integrity of the process ensuring that controlled substances are manufactured and distributed only as provided earlier in the statute. *See, e.g.*, *id.* § 842(a)(9) (making it unlawful for any person "who is a regulated person to engage in a regulated transaction without obtaining the [required] identification"). Section 843 then contains miscellaneous provisions further targeting the illegal manufacture or distribution of controlled substances. Section 843(a)(6) in particular is a precursor statute reaching conduct that although not itself involving a controlled substance nonetheless facilitates the illegal manufacturing of controlled substances—namely, the possession of materials with the knowledge or intent that those materials will be used to manufacture controlled substances. It would make little sense to prohibit the possession of, for example, a very specific type of flask but not other lab materials or mixing containers used for the same illegal purpose—hence the choice of the very broad terms "any equipment, chemical, product, or material." In the context of the whole statute then, the four specifically identified items preceding the broad terms are best understood as simply examples of commonly abused equipment or materials and should not be read to constrain the broader language that follows.

But even if the court considered § 843(a)(6) in isolation, the *noscitur a sociis* and *ejusdem generis* canons cannot save Mr. Tew's reading because the water bottles he sold in his poppyseed kits are functionally in the same class as at least the three-neck round-bottom flask. A three-neck

round-bottom flask is useful for distilling, mixing, and storing chemicals. In a similar way, water bottles are useful for mixing and storing liquids. Just as a drug-manufacturer may use a three-neck round-bottom flask to mix otherwise-licit substances to produce something illicit, Mr. Tew's seed-straining water bottles were used for mixing otherwise-licit unwashed poppy seeds with water to distill a tea containing illicit substances.

That settles the first issue; the water bottles he sold fit comfortably within the scope of "any equipment . . . [or] product." The remaining issue is the effect of the poppyseed exclusion. As noted above, poppyseeds are explicitly excluded from regulation under the Controlled Substances Act even though poppy plants are controlled. *See id.* § 802(19)–(20). So, Mr. Tew argues, this case involves no controlled substance to which § 843 could possibly attach criminal liability, and he cites for support *United States v. McCarthy*, 2025 WL 360952, a district-court case dismissing part of an indictment brought under the same statutory section on facts similar to those here. In the court's view, neither the statutory exclusion nor *McCarthy* support his position.

The statutory exclusion cannot help Mr. Tew because this case is about more than innocent poppyseeds. Mr. Tew curiously overlooks the three controlled substances that he intended his customers to extract using the poppyseeds and water bottles he sold—morphine, codeine, and thebaine. Even though Mr. Tew himself did not possess these controlled substances in a form that the Act prohibited, the evidence as alleged leaves no doubt that he at least knew that his customers were using the poppy seeds and water bottles to manufacture controlled substances.

As for *McCarthy*, it at first glance appears highly persuasive for Mr. Tew's position. The defendants in *McCarthy* operated an online retailer for products like chia seeds, flax seeds, and vanilla beans. They caught the government's eye, however, because nearly all their sales involved unwashed poppy seeds. And like Mr. Tew, they provided detailed instructions for making

poppyseed tea using the unwashed poppy seeds. *Id.* at *1. On the defendants' motion, the *McCarthy* court dismissed the substantive possession and precursor charges, reasoning that poppyseeds were neither controlled substances nor "equipment, chemical[s], product[s], or material[s]" within the meaning of § 843. *Id.* at *6–7, *9.

Despite the superficial similarities between *McCarthy* and this case, the government's theory of the evidence is meaningfully different here. In *McCarthy*, the government argued that the poppyseeds themselves were a controlled substance (for the substantive possession charge) and "product[] or material" (for the precursor charge). That is, the government there tried to impose liability based on the poppyseeds alone, without pointing to some other material for the precursor charge. The court rightly rejected the possession argument given the statutory exclusion for poppyseeds and rightly rejected the precursor argument because poppyseeds are not "mechanical, industrial, or otherwise manmade items," unlike three-neck round-bottom flasks, tableting or capsuling machines, or gelatin capsules. *Id.* at *9.

In this case (which of course concerns only a precursor charge, not a substantive possession charge), by contrast, the government argues that the water bottles constituted "equipment . . . [or] product[s]" satisfying the precursor provision. The question in this case therefore is whether water bottles fit within the scope of the precursor provision—a question the *McCarthy* court never confronted—and the *McCarthy* court's reasoning that poppyseeds do not fit within the scope of that provision accordingly does little to change the court's conclusion that the water bottles fit comfortably.

Finally, Mr. Tew makes a slippery-slope argument—that siding with the government here would expose innocent individuals to liability from ordinary household objects. He gives the example of a baker using a mixing spoon to prepare poppyseed muffins, suggesting that the spoon

would be "equipment" within the meaning of § 843. The court is unmoved. Although the terms "any equipment . . . [or] product" are broad enough on their own to cover a mixing spoon, the scope of the statute is crucially limited by the phrase "knowing, intending, or having reasonable cause to believe[] that it will be used to manufacture a controlled substance or listed chemical." *Id.* § 843(a)(6). A baker using a mixing spoon to make poppyseed muffins for breakfast would not face liability under the Controlled Substances Act because he is not using his spoon to manufacture or distribute illicit substances.[1] For these reasons, Mr. Tew's challenge to the charge of unlawful possession of drug-manufacturing paraphernalia fails.

II. Sale of Home Donor Kits

As noted above, Count 3 charges Mr. Tew with failure to follow regulations governing the manufacture and distribution of human tissue in violation of 42 U.S.C. §§ 264 and 271(a). Section 264 (also known as § 361 of the Public Health Service Act) grants the Surgeon General the authority to "make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases . . . from one State or possession into any other State or possession." 42 U.S.C. § 264(a). Due to subsequent changes in the structure of the agencies involved, "the FDA is empowered to issue regulations under [§ 264]." *Indep. Turtle Farmers of La., Inc. v. United States*, 703 F. Supp. 2d 604, 619 (W.D. La. 2010). Exercising that authority, the FDA has promulgated regulations requiring manufacturers of human cellular and

[1] In case it is not obvious, poppyseed muffins are not illicit substances the way that poppyseed tea is. Although consuming poppyseed muffins can lead to a positive urine drug test for opiates, poppyseed muffins are not intoxicating. *See* Gary Reisfield, *Can Eating Poppy Seeds Affect Drug Test Results? An Addiction and Pain Medicine Specialist Explains*, UNIV. OF FLA. HEALTH (Feb. 28, 2023), https://ufhealth.org/news/2023/can-eating-poppy-seeds-affect-drug-test-results-addiction-and-pain-medicine-specialist.

tissue-based products, including semen, to register with the FDA and requiring donors to be screened and tested. 21 C.F.R. § 1271.1(a) (the portion of subpart A of § 1271 setting out regulatory purposes); *id.* § 1271.3(d) (the portion of subpart A stating that semen is considered a cellular or tissue-based product); *id.* §§ 1271.21–.37 (subpart B specifying procedures for registration); *id.* §§ 1271.45–.90 (subpart C specifying requirements for donors). The regulations provide two related but distinct exemptions for the transfer of reproductive cells or tissue to a sexually intimate partner of the donor. *See id.* §§ 1271.15(e), 1271.90(a)(2).

The specific requirements set out in the regulations are not necessary to explain here; suffice to say that Mr. Tew did not follow any of the requirements for manufacturers or donors. He argues, though, that he was not required to follow those requirements for three reasons: First, according to his reading of § 264, the registration and screening obligations can apply only when the government has reason to believe that the individuals or cells at issue are infected or contaminated. Alternatively, he argues that § 264 applies only to animals and things. Third, considering that the regulations do not define "sexually intimate partner," he claims he is entitled to the sexually-intimate-partner exemptions.

The latter argument is patently frivolous. Under no reasonable understanding of "sexually intimate partner" may Mr. Tew avail himself of either of those exemptions. Mr. Tew interacted with his customers online and shipped his semen by common carrier. The extent of his relationship with his customers was that characteristic of an arms-length business transaction and bears no resemblance to any sexually intimate relationship.[2]

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[2] Mr. Tew appeals to the rule of lenity, which "requires that unclear penal statutes must be construed in favor of the accused." *United States v. Fillman*, 162 F.3d 1055, 1058 (10th Cir. 1998) (internal quotation marks omitted). But crucially, "[t]he rule's application is limited to cases where, after

Returning to his first argument, the court sees the statute differently. As mentioned above, § 264 broadly permits "regulations as . . . necessary to prevent the introduction, transmission, or spread of communicable diseases . . . from one State or possession into any other State or possession." 42 U.S.C. § 264(a). Screening and testing requirements for sperm donors plainly help prevent the spread of communicable diseases and therefore fit neatly within this grant of "broad, flexible powers to federal health authorities." *Cf. Louisiana v. Mathews*, 427 F. Supp. 174, 176 (E.D. La. 1977).

Mr. Tew argues, however, that other language in § 264 suggests that any regulatory obligations may apply only after the government has reason to believe that the individuals or cells in question are infected or contaminated. For example, § 264(a) goes on to say, "For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, [and] destruction of animals or articles *found to be so infected or contaminated as to be sources of dangerous infection to human beings* . . . ." *Id.* (emphasis added). And under § 264(d)(1), "[r]egulations . . . may provide for the apprehension and examination of any individual *reasonably believed to be infected with a communicable disease*." 42 U.S.C. § 264(d)(1) (emphasis added).

Mr. Tew's argument focusing on this other language largely ignores the broad grant of rulemaking authority in § 264(a). That subsection, once again, grants authority "to make and

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reviewing all available relevant materials, the court is still left with an ambiguous statute." *Id.* (alteration in original) (internal quotation marks omitted). Nothing about the statutory language "sexually intimate partner" is ambiguous, at least not in the context of Mr. Tew's online business activity. Needless to say, not one of Mr. Tew's customers was a sexually intimate partner of his because none of them ever had sexual intercourse—or any physical contact for that matter—with him.

enforce such regulations as . . . are necessary to *prevent* the introduction, transmission, or spread of communicable diseases." *Id.* § 264(a) (emphasis added). The face of the provision indicates that it principally permits preventative regulations—that is, regulations that keep diseases from spreading in the first place. The other language that Mr. Tew points to is best understood as clarifying that the regulations may also provide for specific measures to be taken against animals, articles, or individuals found to be infected. For example, regulations could provide for the "destruction of animals" or the "apprehension and examination of . . . individual[s]." *Id.*; *id.* § 264(d)(1). Indeed, subsection (d) is titled "Apprehension and examination of persons reasonably believed to be infected." *Id.* § 264(d). Section 264 read holistically, then, tells the FDA essentially this: "You may promulgate regulations to prevent the interstate spread of disease from animals and humans; you may take more drastic measures, such as destroying animals or apprehending people, if you find them to be infected." To use the language concerning already-infected animals and individuals to restrict the scope of the FDA's authority would be to turn § 264 on its head and render the FDA largely powerless to do anything proactively to keep diseases from spreading in the first place—in clear contradiction to the grant of rulemaking authority in § 264(a).[3]

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[3] Mr. Tew cites the Supreme Court's decision in *Alabama Ass'n of Realtors v. Department of Health & Human Services*, 594 U.S. 758 (2021), which concluded that the Centers for Disease Control and Prevention ("CDC"), which also has authority to promulgate regulations under § 264, overstepped that authority in imposing an eviction moratorium. That decision, though, does not support his position because regulating the transfer of semen from a man to his customers is much closer to the measures identified in the statute as potentially necessary for preventing interstate transfer of disease than was the CDC's eviction moratorium.

The CDC's position for why the moratorium was necessary to prevent the spread of COVID-19, as expressed by the Court, was that "[if] evictions occur, some subset of tenants might move from one State to another, and some subset of that group might do so while infected with COVID-19." *Id.* at 763–64. In rejecting this position, the Court explained, "This downstream connection between eviction and the interstate spread of disease is markedly different from the direct targeting of disease that characterizes the measures identified in the statute." *Id.* at 764. The key words are

As to Mr. Tew's argument that § 264 applies only to animals and things and not to individuals, the court is not persuaded, most fundamentally because the statute grants broad regulatory authority to prevent the interstate spread of disease, and regulations on sperm donation fit comfortably within this delegation. But even if the court adopted Mr. Tew's narrower reading of the statute, it would still authorize the regulations that he failed to follow. The language the statute uses is "animals or *articles*," *id.* § 264(a) (emphasis added), and under the regulations, "semen is considered" an "*article[]* containing or consisting of human cells or tissues . . . [when] intended for implantation, transplantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d) (emphasis added). The statute thus authorizes the regulation of semen, at least in settings like Mr. Tew's (since he intended his semen to be transferred into his customers), and insofar as the regulation regulates Mr. Tew as an individual, it does so incidentally because he "engages in the manufacture of human cells, tissues, and cellular and tissue-based products." *Id.* § 1271.3(b).

Mr. Tew makes in addition two Due Process Clause arguments for dismissing Count 3: that § 264 and its attendant regulations are void for vagueness and that they violate his substantive due-process right to privacy. Neither one holds water.

The Due Process Clause of the Fifth Amendment provides that "[n]o person . . . shall be . . . deprived of life, liberty, or property, without due process of law." U.S. CONST. amend. V. This Clause requires that Congress (or federal agencies) "give people of common intelligence fair notice of what the law demands of them" before imposing punishment for violations of statutes

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"direct targeting of disease." That is, § 264 authorizes agency regulations that directly target disease. It is hard to imagine regulations more directly targeted toward diseases carried through semen than the FDA regulations requiring screening and testing for sperm donors.

and regulations. *United States v. Davis*, 588 U.S. 445, 451 (2019) (internal quotation marks omitted). A statute or regulation is unconstitutionally vague and therefore void if it "has no core"—that is, if it has no "ascertainable standard for inclusion and exclusion [of conduct]." *Smith v. Goguen*, 415 U.S. 566, 578 (1974). A good example of a statute with no core is a statute that asks judges "to disregard how the defendant actually committed his crime" and instead "imagine the idealized 'ordinary case' of the defendant's crime and then guess whether [the statutory language would apply to that ordinary case]." *Davis*, 588 U.S. at 452 (cleaned up) (discussing *Johnson v. United States*, 576 U.S. 591 (2015)). The reason such a law is void for vagueness is that it "produces [excessive] unpredictability and arbitrariness." *Johnson*, 576 U.S. at 598.

The regulation at issue here poses no such concerns. Any "establishment" (defined to include "individual") that "manufactures" cellular or tissue-based products, including "semen," must "register . . . with the [FDA] . . . and . . . comply with the other requirements contained in [21 C.F.R. §§ 1271.1–.440]." 21 C.F.R. §§ 1271.1(b)(1), .3(b)(1), .3(d)(3). That is, unless either of the sexually-intimate-partner exceptions applies, and no reasonable person would think that an arms-length online business relationship constitutes a sexually intimate relationship. These provisions put Mr. Tew on full notice that his conduct required him to register with the FDA and comply with the regulations in Part 1271.

Mr. Tew's insistence that the regulation is unconstitutionally vague builds on his earlier arguments that the court has already rejected. For example, he argues that the enabling statutory provision, § 264, permits regulation only if the article in question is found to be infected and that it is not clear what kind of infection counts. Further, he argues that it is not obvious when the sexually-intimate-partner exceptions may apply. Once these arguments are dismissed for the

reasons above and the plain operative statutory and regulatory language is brought into focus, no vagueness problem exists.

Apart from prohibiting excessively vague laws, the Due Process Clause also protects certain fundamental rights and liberties against government infringement unless the infringement passes strict scrutiny. *Reno v. Flores*, 507 U.S. 292, 301–02 (1993). In deciding whether a right is fundamental for substantive due-process purposes, the court must ask "whether the right is deeply rooted in our history and tradition and whether it is essential to our Nation's scheme of ordered liberty." *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 237 (2022). Fundamental liberties include the right to marry, *Loving v. Virginia*, 388 U.S. 1, 12 (1967), to have children, *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535, 541 (1942), to direct the education and upbringing of one's children, *Meyer v. Nebraska*, 262 U.S. 390, 400 (1923); *Pierce v. Soc'y of Sisters*, 268 U.S. 510, 534–35 (1925), and to exercise marital privacy, *Griswold v. Connecticut*, 381 U.S. 479, 485–86 (1965). As the list above suggests, fundamental rights "for the most part . . . relat[e] to marriage, family, procreation, and the right to bodily integrity." *Albright v. Oliver*, 510 U.S. 266, 272 (1994) (plurality op.). Mr. Tew argues that the statute and regulations at issue in this case impermissibly intrude on his fundamental right to procreate by restricting his donation of semen.

Perhaps Mr. Tew is correct that the right to donate semen for reproduction is a fundamental right in the context of marriage or some other family relationship. But in the context of this case, the right at issue is better characterized as the right to sell one's semen to unrelated third parties in arms-length business transactions. Again, taking the facts in the light most favorable to the government, Mr. Tew did not give his semen to his spouse or partner for the purposes of starting or growing his family. Instead, he sold his semen to unrelated women whose children, if he ended up fathering any, would have no relationship with him. *Cf. Erotic Serv. Provider Legal Educ. &*

Rsch. Project v. Gascon, 880 F.3d 450, 455–56, 459 (9th Cir. 2018) (explaining that prostitution, even when it involves sexual relationships between consenting adults, is not a fundamental right because it is commercial rather than intimate in nature). Although Mr. Tew's conduct in a sense literally implicates his right to procreate, it does not implicate the kinds of intimate personal relationships whose regulation triggers heightened scrutiny. *Cf. Lawrence v. Texas*, 539 U.S. 558, 567 (2003) ("When sexuality finds overt expression in *intimate conduct* with another person, the conduct can be but one element in a *personal bond that is more enduring*." (emphases added)). The court is not aware of any other court to have held that the right to sell semen in commerce is a fundamental right for substantive due-process purposes, and this court will not be the first.

CONCLUSION AND ORDER

For the reasons above, the court **DENIES** Mr. Tew's motion to dismiss Counts 1 and 3 of his indictment.

Signed July 7, 2025.

BY THE COURT

Jill N. Parrish
United States District Court Judge